UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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FERRING PHARMACEUTICALS, INC., ET AL.,

Plaintiffs,

v. 17 CV 9922 (RWS)

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC,

Defendants.

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New York, N.Y.
March 14, 2018
12:03 p.m.

Before:

HON. ROBERT W. SWEET,

District Judge

APPEARANCES

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(In open court)

(Case called)

THE COURT: Please be seated. Thank you very much. Ferring.

MR. HARNETT: Yes, your Honor. Chris Harnett arguing on behalf of Serenity and Reprise. The Court convened a pretrial scheduling conference, the initial pretrial scheduling conference, with the parties in connection with the case that was transferred from the District of Delaware on February 21st, and we convened in chambers. Your Honor issued the order that set today as the oral argument date for our motion to dismiss for lack of subject matter jurisdiction.

As part of that order, your Honor asked the parties to provide you with courtesy copies of all the papers that were submitted in Delaware, which we've done. In so doing, we realized that our motion to dismiss was filed as part of a combined motion with our motion to transfer the case from the District of Delaware back here. And in order to avoid any confusion, we took your Honor up on the other part of the February 21st order and that was to submit a supplemental brief by last Friday.

In that supplemental brief, we tried to, in a very concise form, I think we limited that to ten pages or so, a very concise form to crystalize what we thought were the key arguments that we wanted to discuss about our pending motion to

dismiss, which is being heard by your Honor today.

In that regard, we've also prepared a few slides that will help us assist with the oral argument. People can't do arguments without slides anymore, and with your Honor's permission, I'll hand them up.

THE COURT: Sure.

MR. HARNETT: There was an interesting story on NPR once that blamed the Challenger disaster on powerpoint because the O-rings were discussed on page 23 of a powerpoint and nobody paid any attention to them.

Okay. The crux of our argument is there's no subject matter jurisdiction. The declaratory judgment action that Ferring brought against Serenity/Reprise in the District of Delaware. There is no case or controversy of sufficient immediacy to impart subject matter jurisdiction for Ferring to bring this declaratory judgment action challenging the validity of Dr. Fein's three patents.

As we'll describe in more detail, and we described in our papers, there is absolutely no reliable evidence, none, that the FDA is poised, as Ferring suggests, to imminently approve Ferring's Nocdurna product. That product has been rejected over and over again for the past eight years, and all of the evidence from the FDA that is of record shows that the FDA remains extremely concerned about the safety profiles and the advocacy of the Nocdurna product.

The notion underlying Ferring's argument that product approval is imminent is nothing but wishful thinking. The evidence from the FDA, if anything, suggests that Ferring's product will never be approved, much less approved anytime soon.

As a consequence of that lack of immediacy, because there is no immediate case or controversy that your Honor needs to resolve, Ferring is effectively looking for an advisory ruling that Dr. Fein's three patents are invalid. We submit to your Honor that, under rule 1 of the Federal Rules of Civil Procedure, Serenity and Reprise, two relatively small companies who are working very hard now to get their approved Noctiva product to the market, should not be burdened with the time and expense necessary to defend against Ferring's challenge to Dr. Fein's three patents that protect that patented product.

The procedural history of this case and the FDA record, the actual statements of the FDA, not the wishful thinking of Ferring, show that this case should never have been brought, and it should be dismissed now.

So let's talk a little bit about the three patents that are at issue here. This Court has a considerable amount of experience with those three patents in suit. They are Dr. Fein's '203, '321 and '761 patents, and those three patents were the subject of the lawsuit that Ferring brought in this court way back in 2012.

Back in 2012, when Ferring brought its complaint directed to those three patents of Dr. Fein's, Ferring argued that Ferring should be the inventer of those patents, not Dr. Fein. Ultimately, over the course of five years of litigation, your Honor rejected Ferring's 14 separate state law causes of action directed to those three patents, and based on the grounds of equitable estoppel, ruled that Ferring could not properly challenge -- make a federal inventorship challenge to those three patents for which Dr. Fein is the inventor. Your Honor granted summary judgement under equitable estoppel that Ferring could not be the -- challenge the invention of those patents.

So what happened then? After your Honor's rulings, Ferring ran off to Delaware, and if we look at the first slide, slide No. 1, Ferring didn't come to this court and challenge the validity of those patents. No. What did Ferring do? Before the equitable estoppel, in looking at slide 1, Ferring's position was Dr. Fein's three patents were, A, that Ferring was the rightful owner of them; two, that there were very valuable inventive contributions of Ferring scientists; and that they were worth tens of millions of dollars. That's what Ferring told your Honor. That's what Ferring told this Court.

Then, after your Honor granted our motion for equitable estoppel, things changed dramatically. They ran off to the Delaware, and they presented a series of absolutely

irreconcilable arguments. Down in Delaware, they argued, well, these patents are actually worthless. They're no longer the valuable contributions of Ferring's inventors. They're invalid for six different reasons. The same -- these are the patents that they read. They knew about them. They said they were valuable. They spent five years of your Honor's time saying that they should be the rightful owner, and they should collect damages. They must have read the patents.

But now, suddenly, after your Honor's equitable estoppel ruling, they're worthless. They're invalid for six different statutory reasons, as well as a specious charge of inequitable conduct on Dr. Fein's part.

So we believe that, first of all, the assertions that underlie Ferring's complaint here are utterly irreconcilable are positions than they've taken previously with this Court. In fact, if this case ever goes forward, and we don't think it should because there's no case or controversy, we think that Ferring has already conceded the validity of these patents.

But we look at the next slide. The next slide is a timeline of Ferring's rather gymnastic efforts to avoid this Court, after the equitable estoppel. They turned cartwheels to never have this motion to dismiss heard in this Court. They ran off to Delaware. They filed the first complaint. They filed a second complaint. They asked for extra briefing every step along the way.

Even after Judge Sleet transferred the case back to this Court, they filed a motion for reconsideration of the transfer motion, which never has been granted in Delaware in any case. Notwithstanding the fact that Delaware is firing on 50 percent vacancies on the bench, they asked for rehearing on their motion to transfer. And even after the case was formally transferred up to this Court and the clerk wheeled it to Judge Hellerstein, Ferring argued it wasn't a related case after all.

It didn't matter that your Honor spent five years on the dispute related to these three patents, the same parties, the same parties' businesses, the same parties' product. They didn't want this Court to ever hear this case or this motion because of the irreconcilable positions taken here for five years and taken there in Delaware.

So that procedural history is by way of background, and I think it highlights the lack of case of controversy and the lack of merits as to the underlying case. Your Honor may remember, if we turn to slide three, Ferring and Serenity have been trying to get competing products through the FDA. Serenity succeeded. Serenity got Dr. Fein's -- based on Dr. Fein's inventions, Serenity got its Noctiva product approved in March.

Ferring, on the other hand, has been trying unsuccessfully for nearly nine years to get its product approved. The FDA, in the course of that nine-year review

process, has issued three complete response letters rejecting Ferring's application. And as part of that, the three complete response letters, the FDA convened an advisory committee of expert physicians, regulators, people who really know what they're doing, and the advisory committee voted overwhelmingly against Ferring's product. It has been an utter failure in the FDA.

The FDA has never indicated any willingness whatsoever to approve that product. But undeterred by that, it's bad enough that Ferring has kept trying to get its product approved, they actually tried to stop Serenity's product from getting approved as well. They filed a citizen's petition, saying, okay, you're not approving our product, don't approve Serenity's product either.

Well, that was last March. Last March the FDA drew a line in the sand, said, nope, Serenity's product is safe and effective. Yours is not. We're denying your citizen's petition. Serenity gets approval. You don't. You don't get to stop Serenity from getting approval.

And what you see on slide three is an undisputedly accurate timeline that was published in this journal -- in this publication called the pink sheet. The pink sheet is basically the daily, weekly -- I forget which way it comes out -- legal publication letting the world know who's getting approved, what drugs are doing what.

So the title of this article is "Tale Of Two Desmopressins," it's kind of clever. One was Serenity's desmopressin product, Noctiva, and one was Ferring's desmopressin product Nocdurna. And what this shows that April 22nd, 2010, the FDA rejects Ferring's product. January 2013, another complete response letter refusing to approve the product. August 2013, still no good. January 2015, the advisory committee convenes and votes against it. And right after that, the FDA grants another, the third complete response letter, saying no approval. And then in March of 2017, they deny -- the FDA denies Ferring's citizen's petition trying to keep Serenity's approved product off the market.

So you heard a lot during the trial last month about something called hyponatremia. Dr. Fein testified about it. Dr. Susman testified about it. It's a very serious side effect that can happen from the administration of desmopressin. Desmopressin drugs like Ferring's proposed Nocdurna product. So serious, in fact, that it can cause comas, seizures, cardiac arrest. That's about as serious as it gets.

And if you look at slide four, this is the vote of the FDA advisory committee that the FDA convened to consider Ferring's application. The simple question that was asked is: Does the demonstrated benefit of Nocdurna -- Ferring's product -- outweigh the risks and support approval for nocturia

due to nocturnal polyuria? Ten no votes, only five yes votes, two abstained, and included among the no votes were several cardiologists. And, of course, cardiologists are doctors who are concerned about disorders of the heart, the most profound of which is cardiac arrest.

So if you read the notes, which are attached as Exhibit A to our supplemental brief, of the advisory committee meeting, the advisory committee specifically says the risk of hyponatremia was a motivating factor behind the decision not to approve Ferring's product.

Okay. So where are we in terms of the record of this case? When Ferring ran off to Delaware, it was in April of last year. The declaratory judgment complaint that Ferring filed was timed to coincide with Serenity's efforts to find a new commercial partner after Allergan left the agreement. So there's Dr. Fein and Serenity trying real hard to find another marketing partner. They get sued in Delaware challenging Dr. Fein's three patents.

And what's the evidence? According to Ferring, Ferring says, we need to have an immediate declaratory judgment action where we get to challenge the validity of these patents because we're about to get, imminently -- those are the words that Ferring uses -- imminently going to get approved by from the FDA.

What do we have in the record from the FDA? Well, I

showed you everything we had up until March of 2017. That's the history of repeated rejections, and then there's the FDA also rejected Ferring citizen's petition. The two most recent documents are in the record today supposedly supporting subject matter jurisdiction are a March 3rd letter from Dr. Janet Woodcock, and that was the letter explaining the reasons why the FDA rejected Ferring's citizen's petition, and then we have the March 6th minute meetings of a telephone conference between certain FDA representatives and Ferring.

A year has gone by since then. A year has gone by, and we have not seen a -- Ferring has the burden of proving subject matter jurisdiction here, and a year has gone by and we have not seen another piece of paper. Your Honor gave them, Ferring, an opportunity, gave us an opportunity to put in supplemental briefs last Friday. We did. They didn't. Presumably, if the FDA was poised to imminently approve this product, there would be some piece of paper somewhere that says so, but there isn't.

The last two pieces of paper reflecting the FDA's thought process are more than a year old and both of them show that the FDA is highly skeptical about the product, that the FDA remains very much concerned about the risk of hyponatremia, and the FDA has not retreated from its position that the risk of hyponatremia outweighs the minimal benefit that has been shown by Nocdurna.

So let's look at the letter from Dr. Woodcock. That's at slide five, and these are some quotes from the letter. And let me summarize. I used to be a bench scientist before I went to law school. I wasn't a very good one, and so my lab director was quite happy that I applied to law school. And there was an expression that's used in scientific labs; it's called garbage in, garbage out. Bad study design gives rise to bad data. Bad data generates bad conclusions all the way around.

What Dr. Woodcock said, cutting through, summarizing her arguments in the citizen's petition response, she explained why the FDA was absolutely right in granting Serenity's application and denying Ferring's application. Serenity's test -- its clinical study design was good. Ferring's was not. The problem with Ferring's design are a couple. It's divorced from the real word use of desmopressin, and that's a quote from Dr. Woodcock, who's the boss. She is the FDA's chief drug approval officer.

She expressed concerns that Ferring's study design would significantly understate the incidence of hyponatremia. And why? She explained why. Ferring's clinical studies allowed patients as young as 18 to be enrolled. Serenity's study design was older people. Who gets hyponatremia? Who needs this drug? Older people. No 18-year-olds. No college soccer teams are taking desmopressin because they're going to

the bathroom in the middle of the night. It's old people. And their study design had a disproportionate cohort of young people, which would have displaced older people, who were more susceptible to hyponatremia.

The other thing, Ferring's study included specific patient instructions that said, don't drink before you go to bed at night, don't have any alcohol, don't have any caffeine. All probably pretty good advice, but it's a confound in the data. If you're telling the patient don't drink before bed, it's not what's going to happen in the real world. So if it shows any -- if the data shows any efficacy, it's contaminated. You can't tell whether the reduction in the number of times one has to go to the bathroom is a function of the fact that they didn't drink before bed, they stopped using caffeine, or they stopped using alcohol, or the fact that the drug really works. So Dr. Woodcock said that this study, Ferring's study, design is flawed.

Now, I'm going to move on to the next piece of documentation we have from the FDA, but it's very important to note that what Ferring is trying to do now with the FDA is to take this very same test data, the very same data from the very same experiments that the FDA has rejected repeatedly, that Dr. Woodcock has criticized the design of, and all they're doing is going back to the FDA and say, hey, give us an opportunity to reanalyze the test data and try again.

Because they've paid their application fee, under statutes and regulations, the FDA, they'll look at it, and that's all we've got. The FDA has never said, oh, yeah, we think we're going to approve this. I'll show you exactly what the FDA said, but before I do, let me just point out one thing, and maybe something will change today. In the mountain of briefing you've seen on the motion to dismiss, Ferring never once has said a word about Dr. Woodcock's criticism of the study design. They've just ignored it over and over again. And this is the same study design that's the basis of their ongoing application.

So let's look, the March 6th meeting minutes, that's slide six. This is the last word we have in the record from the FDA, and what does it say? Based on the fact that, according to Ferring, I think their argument is -- it moves around a little bit. I think their argument is, by virtue of the fact that the FDA is willing to let them submit the reanalyzed data for analysis, that means something good is going to happen. It doesn't. It simply means that they paid their fee and the FDA will review it.

Look at the exact words. That's what the FDA said. This is a: "The FDA noted that Ferring's NDA submissions to date have not provided convincing evidence of a clinically meaningful treatment benefit for Nocdurna." Also, they said that, as part of any ongoing submission, Ferring has to submit

a proposal for mitigating the risk of hyponatremia, the thing that can kill you.

We've heard Ferring argue that, oh, at this point, safety is a done deal. They passed on safety. Uh-uh. The last document from the FDA shows that they're still concerned about hyponatremia. The FDA cautioned it's unclear whether the reanalysis of the data will result in a positive outcome, and they're not going to be able to tell Ferring until they've reviewed the whole thing.

We have not seen a paper, the Delaware court has not seen a paper, your Honor has not seen a paper dated after March 6th. This is what they're hanging their hat on that approval is imminent, and it's a year old, and there's nothing more. And you gave them an opportunity to show more and they didn't.

So in the absence of any documents from the FDA, what does Ferring do? In their first amended complaint down in Delaware, they submitted the declarations of two witnesses, two declarants. Who are they? One of them is their outside lawyer. His name is Mr. Fox. One of them is Ferring's project manager. Her declaration basically says, I read Mr. Fox's declaration, I agree with it, and they both say, we're optimistic. We think there may be some approval.

But we tested this. Right? Let's look at -- when we had Mr. Fox, we asked for Mr. Fox's deposition and one thing we

showed him was the statements from the meeting minutes of March 6th, and that's on slide seven. We've lined up some of the FDA statements, and we've lined up what Mr. Fox says about them.

When the FDA says, oh, you got to be concerned about hyponatremia. We can't promise you anything. We'll review it. To date, you haven't shown anything. What does he say? Ahh, this is standard disclaimer language. This is something people could quibble with. These are just theoretical possibilities.

Now, I invite your Honor to read the meeting minutes. These are serious people at the FDA. The FDA is concerned about possibly approving a drug that could stop your heart. They're not just saying things that you might quibble with, mere theoretical possibilities. This is serious business, but that was the level of testimony that we got from their witness, their paid lawyer, who testified that he was paid for the declaration, that he was paid for the time preparing for the deposition, that he expected to submit a bill for the time he spent giving deposition testimony. He was an advocate and not a witness.

Now, it got so bad -- I had some questions that he adhered so closely to the party line, he would not answer any questions directly. One question I couldn't help myself but ask him: Hyponatremia is a bad thing, right? The answer to that is yes. It has to be yes. Any honest answer to that is

yes. Look at the answer he gives. Well, it is what it is. It's a side effect of the drug. Yeah. It's not serious testimony. It's not something that creates an actual legitimate case or controversy that opens up subject matter jurisdiction that should require Serenity divert its resources from getting its product on the market to defend against a specious challenge to its three patents, the same three patents that Ferring said were the most valuable thing since sliced bread when they were in front of your Honor five years ago.

Let me just say a few more words about the deposition testimony here, and the reason I'm going to do that is because during our conference in chambers last month, counsel for Ferring made a couple of references to the order from Judge Sleet down in Delaware when he granted the motion to transfer. He denied Ferring's motion to submit an unauthorized surreply brief and the motion to dismiss as moot. And your Honor said you'd allow it; fine, we'll take it on the merits, and that's what I'm going to do now.

The whole gist, the whole gravamen of Ferring's motion for leave to file a surreply, which is not authorized under the Delaware rules, but was to take on the arguments that we presented about the problems with their witnesses' testimony, and that was the whole point of the surreply brief. And they basically -- we showed in our last paper that these witnesses -- that their testimony shouldn't be credited.

I just want to give you a couple of examples here. This is another excerpt from Mr. Fox's deposition. One question: In your declaration you say that they -- being the FDA -- have to balance the efficacy against the risk of hyponatremia, right? Now, a deposition testimony is no different from the court testimony. It's like someone sitting up there in the witness stand. If someone was sitting right there in the witness stand, your Honor would say: Answer the question. The answer to that question is yes.

What did I get? I got 232 words of double speak. Read it. Count one to 232 in your head, see how long that takes. That's the kind of answer I got to virtually every question I asked Mr. Fox, who is being put up to justify a declaratory judgment action when the FDA is not in any position or has given no indication they're going to approve the product.

And if you look, there's some great irony here on the next slide, when in that motion -- in that surreply brief Ferring took the position, oh, we're being unduly critical and harsh about Mr. Fox's testimony. What he really was giving was thoughtful and fulsome testimony. Those are quotes, thoughtful and fulsome.

But even when Ferring tried to -- wanted to quote Mr. Fox, they quoted him, and this is another quote, in part. They quoted 58 words of a 205 word answer. The whole

deposition was a filibuster. It was just a statement of the party line. It was not the sort of testimony that can support declaratory judgment jurisdiction.

The other witness was a woman named Ms. Tina Olson. She's the project manager, and it was pretty clear that Ferring, the whole point of -- one of the points of Ferring's surreply is they wanted the entirety of Ms. Olson's transcript in the record because at the very back of it Ferring's counsel asked Ms. Olson a series of opinion questions. Well, Ms. Olson, in your opinion, is the FDA going to approve the product? In your opinion, is the FDA satisfied that hyponatremia is not a problem? X, Y and Z.

We objected, and on redirect we established, well, Ms. Olson is in no position to give that kind of opinion testimony. Her degree is an MBA. Her background is in business administration. Her whole -- in her whole life, she's had experience with three NDAs. She's not a medical doctor. She has no clinical experience. She has no regulatory experience.

Yet, what we basically have here is Ferring has nothing from the FDA; so they're trying to pad the record with stuff from interested and, in one instance, they both are paid witnesses, and that's all a sideshow. What really matters, all that matters here, is does your Honor have evidence in front of the Court that the FDA is imminently poised to approve this

product? And you don't.

What you have, the evidence you have from the FDA is nine years of rejections, a letter from the chief drug approval office saying the study design that you're asking us to reconsider the data on masks the incidence of hyponatremia; it's divorced from the real world; and you have meeting minutes which says, we'll look at your data like we have to do under the statute, but we're not promising you anything. That's what you have.

So what's motivating this, I believe, is Ferring -- if you look at the history of this, Ferring sued Serenity/Reprise here. Ferring sued Serenity/Reprise in Delaware. Ferring provoked proceedings in the PTO for reexamination. Ferring provoked proceedings in the Hague. Ferring wants Serenity and Reprise to divert their limited resources from getting their product on the market, out and running, and pay me. And I don't want them to pay me. They shouldn't have to. They shouldn't have to assume the cost and burden of defending the patents, defending the validity of the patents that Ferring has already conceded about.

To the extent your Honor has any questions, I'm happy to answer them or get up again later. Thank you.

MS. BOURKE: I'm good with the podium, since I'm a little more soft-spoken, and make sure the court reporter can hear me.

Good afternoon, your Honor. Mary Bourke from Womble Bond Dickinson, on behalf of the Ferring plaintiffs. I want to focus on what the issue is that is before the Court. The issue before the Court is whether this Court can exercise subject matter jurisdiction to invalidate a patent when somebody, namely Ferring, fears that they may be sued for infringement. That's what the Declaratory Judgment Act is all about.

We're not here seeking an advisory opinion. We're here for freedom to operate. And I will address the imminency of approval, but the history of the -- we might want to start a little bit with the history, the procedural history of the litigation. First off, just to orient the Court, this is a declaratory judgment action against three patents that name Dr. Fein as the sole inventer, which Serenity and Reprise have asserted that Ferring's oral dispersible dosage form of desmopressin, which is called Nocdurna, will infringe, if approved.

So let's take us back in history. There was the lawsuit in front of your Honor that was filed, that we went to the counterclaim trials on a month ago, was filed in 2012. It was filed as an entitlement claim, and there was no declaratory judgment filed then because we didn't have a basis to do that. There was no imminency of approval. You've heard about how we had struggles with the FDA during that time frame. So that was an entitlement action.

Your Honor issued an opinion that we were too late in bringing that, and we were estopped, equitably estopped. Fine. That's fine. Fast forward, and we'll get to the regulatory history, but the timing of the DJ action has nothing to do with Serenity and Reprise's activities. It has to do with the sea change that occurred within the FDA about how they were viewing these desmopressin products to treat nocturia and specifically how they were viewing the NDA that Ferring had filed for Nocdurna. That's why the lawsuit was brought. There was a sea change, which led to a very strong belief amongst everybody that approval would be imminent.

Let's just address the commentary that was made by counsel for Serenity and Reprise about somehow the actions, the declaratory judgment action is somehow inconsistent with the entitlement action. They're not inconsistent at all. What happened was your Honor told us we were too late to bring our entitlement action. Okay, fine, but we were not too late in bringing a declaratory judgment action.

We brought a declaratory judgment action when we felt we had imminent approval, and the declaratory judgment action is also making the same claims that Dr. Fein is not the sole inventer of those patents. That's the same basis. It's brought under 35 U.S.C. 102F. We're basically saying that those patents are Ferring's intellectual property assets and, quite frankly, if we can't get them back from an ownership

standpoint, we don't want them being used as a sword against us for our soon-to-be-approved product. So that is not inconsistent at all.

Quite frankly, it really is Serenity and Reprise that are being inconsistent here before this Court. They want the Court to believe that there's no imminency of the approval of Nocdurna, yet, in this action. Yet, they are vigorously pursuing the counterclaims for the Ferring patents, which are the formulation patents that we went to trial, in part, on a month ago that cover oral dispersible dosage forms of desmopressin, and the only commercial or economic value of those patents is because they cover Ferring's soon-to-be-approved Nocdurna product.

In fact, in the recent standing briefing that was filed just last Monday night, Serenity and Reprise argued for the first time that they had standing by virtue of its financial interest. Allergan had standing when they brought the counterclaims by virtue of its financial interest in the Ferring patents, and this is, quote, from docket 321 "to the extent the Ferring patents cover any products formulated to deliver low-dose desmopressin, Allergan, as Reprise's exclusive licensee had a financial interest in correcting the ownership of those patents."

The only product that is going to be covered by those patents, it's not their Noctiva product, it's Ferring's

Nocdurna product. They can't have it both ways. They can't, at the one point say they had some financial interest in our patents based on a soon-to-be-approved product, Nocdurna, and then come to this Court in the DJ claims that we brought and say they're never going to be approved.

Finally, they made a point about how Serenity and Reprise have limited resources, they're focused on bringing their Noctiva product to market, and they shouldn't be forced to assume the burden expense with the DJ action. Again, that's inconsistent with them vigorously pursuing this counterclaim trial, which doesn't cover their product Noctiva. The only product those claims of those patents cover, Ferring's patents, is Nocdurna.

Moreover, I would just also explain that, quite frankly, those statements are simply wrong. It's Avadel, the party that I think in the pretrial conference we mentioned we would like to join. It's Avadel that is carrying those expenses, and I have a couple of slides that we can help summarize.

Can we approach? And while we're handing the slides up, you'll recall that the reason that we asked for reargument in Delaware was because Avadel, we learned after the fact, might be needed to be added as a party to the litigation. Avadel was a Delaware corporation.

As an aside, there's nothing wrong with filing a

motion for reargument in Delaware. I've done it all the time and, quite frankly, I've gotten them granted. So I don't understand the statement by counsel that they're not permitted, but leaving that aside, let's take the comment that they have limited resources and they're focusing these resources on the approval of Noctiva and bringing it to market.

If you look at the first slide we have there, you can see that this is from the Avadel license agreement that was -- we found it from an internet search. It's publicly available, but it's redacted in part. But you'll see that there are -- licensee, in this instance, is Avadel, who is the exclusive sub-licensee to the Fein patents, and its licensee at its expense will develop a sales training plan and sales training materials, et cetera. Licensee, at its expense, will train its sales representatives in accordance with such sales training plan and sales training materials. It's the licensee, at its expense, that is developing the advertising and promotional tools. And it's the licensee that's responsible for the manufacture and supply of the product for commercialization.

And what does Serenity do? If you turn to the next slide, it's Serenity just sitting there receiving milestone payments. The initial fee for the license agreement, they got $50 million. When the product launches, they'll get another 20 million. They have commercialization milestone payments, and they receive stacking royalties based on level of sales. These

companies are not destitute. They can afford this lawsuit, just as they can afford the counterclaim lawsuit that they're so vigorously pursuing.

So let's take a look at the regulatory history because I think it's important for the Court to understand what's going on. There was a slide that Serenity put up that tried to show the regulatory history. It was their slide three, and if you turn to my slide four, this is the pre March 2017 regulatory history. We don't dispute it. We don't dispute that we filed the NDA in 2009. We don't dispute that we got three complete response letters rejecting the NDA. That's facts of record. We don't dispute that.

What we do dispute is what the sea change in the FDA occurred after that, and it's important on my slide, for slide four, you'll note that when Ferring filed its NDA back in June of 2009, it was assigned to a particular division within the FDA, which we have a shorthand here DMEP, which stands for the Division of Metabolism, Endocrinology Products.

When Serenity filed its NDA for Noctiva, it was assigned to a different division, a division called the Division of Bone, Reproductivity, Urological Products. And that's significant. Why? Because back in 2009, when Ferring filed its NDA, the desmopressin had been approved for diabetes-type indications. That's why it was assigned to the division dealing with endocrinology.

When Serenity filed its NDA, it was for the indication of nocturia, which is a voiding disorder or urological problem, and so it was assigned to a different division, which composed, in large part, urologists, which understood the unmet medical need for a drug to treat nocturia, which heretofore was not understood. And it also understood how to manage the risk with hyponatremia, which is there for all desmopressin products. It's there for Noctiva, as much as it is there for Nocdurna. And I would just add Noctiva has a big black box warning on its product for hyponatremia.

So what happens? Yes, we filed a citizen's petition. We're entitled to do that. We were concerned that the FDA was going to apply different standards for efficacy and safety to Serenity's Noctiva product relative to Ferring's Nocdurna product. So what happens? The timing is just, it speaks a thousand words. So on the day that they deny our citizen's petition, and before they publicly announce the approval of Noctiva, they pick up the phone and call one of the head regulatory people at Ferring.

That's unheard of in FDA history. Unheard of. Particularly because in the cycle of things, what was outstanding was the 2015 complete response letter. So actions in regard to that were really up to Ferring, but here, we have the FDA picking up the phone, calling us and saying, well, we're going to deny your citizen's petition. We'd like a phone

call with you on March 6th. And in the denial of the citizen's petition, they also invited Ferring to make a similar showing of clinical efficacy based on the existing data that Ferring had already submitted.

Fast forward to the March 17 meeting minutes. This is the other document that Serenity's counsel's talked about. They explain that the -- and this is, for the record, I believe it's Exhibit B to the supplemental briefing -- no, I apologize. It is Exhibit D to the supplemental briefing. But what it says is, on the slide there that's really significant, FDA's thinking has expanded about data that could be used to demonstrate a clinical meaningful benefit for desmopressin drugs to treat nocturia.

So all of this history is summarized in the declaration of Mr. Fox, who, quite frankly, wasn't paid to testify. He has been Ferring's regulatory counsel long before this action was ever filed. He helped Ferring through the regulatory process, and he put in a declaration as to the facts. And, quite frankly, he used to work within the FDA before he became outside counsel; so he understands the workings of the FDA.

He summarizes this history, as does Tina Olson, and basically what happened was there was this sea change. All of a sudden, back in 2015 when Ferring's NDA had been rejected, the FDA had taken the position that Ferring was going to have

to run a new clinical trial with a new patient-reported outcome device. And what happened was, no, they had recognized, through this process, that that was not necessary. They were familiar with our data, which they had said had shown a statistically significant drug effect. And they said, no, you can come back and reanalyze your data, and we'll agree on the five primary endpoints we want you to show, and you don't have to run any other clinical trial, and you don't need a patient-reported outcome anymore.

So based on that activity in March, there was a clear regulatory path forward for Ferring with its NDA, and that hasn't changed. We submitted in our amended complaint, and this is at paragraph 105 -- and this is the next slide, 6 -- we set forth sort of a timetable of things that were to occur. Right? Quite frankly, every single one of those events has occurred as we pled.

Now, did we produce additional documents? No. Because the law is generally that standing has to exist at the time that you file the complaint. So we didn't come in and put in a supplemental pleading, but we can, since they've invited us and they've complained that we haven't produced any additional documents.

We have today additional documents, which we can hand up to the Court and to Serenity and Reprise that demonstrates that every single one of the events that is on slide six

occurred as predicted. In other words, Ferring's NDA is on course for approval in the second quarter of 2018, which we're almost there. We've been playing around for a year on all of these pretrial motion practice and there's been no discovery, no nothing because of this motion to dismiss.

But we have the correspondence that demonstrates that all of these activities occur. You can see on slide seven a formal response to Ferring's submissions of its final revised SAP, that the DBRUP is expected by the end of July 2017. Indeed, we have an e-mail that goes to the regulatory person at Ferring, Brenda: Just to let you know, we have completed our review of your SAP and it is acceptable to the biostatistics review team. Have a great day.

Next event, by August 2017, Ferring will request a formal pre-NDA meeting with the FDA, which should be scheduled for no later than October 2017. Indeed, here we have the letter of August 2017, where we submit a meeting request for as soon as possible.

Indeed, by August 2017 the meeting request was granted, and the meeting was scheduled for October 18, 2017. That's on slide nine.

And, indeed, we submitted the new drug application in December of 2017 with the reanalyzed data and, indeed, the FDA accepted it and, indeed, put out the goal date of June 21, 2018. That's the date that Ferring expects approval. That

date is imminent. We're in March of 2018 now.

With respect to Mr. Fox's testimony and Ms. Olson's testimony, we would invite the Court to read the surreply. We would invite the Court to look at the deposition transcripts. They answered the questions as best as they could. They just didn't give the answers that Serenity's counsel wanted to hear.

So what do the courts look at for subject matter jurisdiction? That's the issue that's before the Court, and so we've summarized them on slide 12, and it's also in our briefs. Are the parties competitors in a field related to the patents in suit? That can't be disputed. Is there a history of litigation between the parties particularly involving related products and patents? I don't think that can be disputed. There are assertions of infringement by the patent holder? I don't think that can be disputed. We'll skip over likelihood of approval because that's all they really seem to dispute. Is the accused product fixed at the time that the relief was sought? It's fixed. There's no formulation required. There's no new clinical data that is going to be generated.

Is it going to be approved? Yes. We fully expect it to be approved in the next couple of months. We need freedom to operate. This product has been approved in multiple countries in Europe and in Canada, and we have all the expectation that it is going to be approved here in the U.S. and the FDA's actions from March of 2017 confirm that. They

were not routine actions. They were out of the ordinary. In fact, I think Mr. Fox called them "extraordinary" based on his experience within the agency.

So we're here today. We'd like to get this case going. We've had no discovery. I have on the last slide, their general objections to our document requests. If you recall, your Honor, when we had the pretrial conference, I told you that they had not responded to our document requests. They still haven't. They won't do it until the motion to dismiss has been decided.

We have outstanding document requests. We have a proposed protective order to provide to them. They are essentially granting their own stay and have done so for a year. That's improper. We have a schedule that was agreed upon and submitted to the Delaware court. I'm happy to hand that up to the Court, if you'd like to see it, but we need to get going because all of a sudden we're going to have approval and who knows what will happen then. We may be faced with emergency motions and other activity, but we filed this nearly a year ago and absolutely nothing's happened. So unless the Court has any questions....

THE COURT: Thank you.

MS. BOURKE: Okay.

MR. HARNETT: May I respond briefly? Two minutes, maybe.

THE COURT: All right.

MR. HARNETT: Just like I said, not a word about Dr. Woodcock's criticism of the clinical trial design, not a word.

Ordinarily, I'd complain. I said when I stood up here that they have not produced a single document from the FDA that was less than a year old. Ordinarily, I'd complain if somebody came to court and said: Here are some documents, I'm going to show them to the judge and you haven't seen them before. I looked at the slides. They don't say anything. They're basically transmittal letters. You submitted the data. All right. The statistical analysis plan? That's acceptable. All that means is the way you're analyzing the data is statistically sound. That doesn't say anything about whether the results are okay. It says, okay, there's a -- what's the exact phrase? The payment fee date of June or July? Yeah. That means you're going to get an answer. What could the answer be? It could be yes, but based on past history, it's not going to be. Based on the fact that they won't say anything about Dr. Woodcock's assessment of the study design, it's not going to be yes. It can be, we need more information; it could be a fourth no. And that's what we think it's going to be.

There's been no agreed-upon schedule. That's just not right. There was never an agreed-upon schedule. There were

competing schedules that were put in in response to the clerk's order. There was no -- it just never happened.

The words from the FDA are the words that matter. The fact that counsel here thinks that there's going to be approval, the fact that people at Ferring are hoping there's approval, that doesn't matter. Read the words from the FDA. The FDA says they're concerned that the drug stops people's hearts. They're concerned that the minimal amount of efficacy that it's shown does not outweigh that risk. It's been that way since the beginning of the case. It's been that way now.

We're not delaying anything. We didn't run off to Delaware and file a lawsuit in a jurisdiction where half the judges are vacant. We didn't do that. They could have filed the lawsuit here, but they ran away because the arguments that they're making here that the patents are invalid are irreconcilable with the argument they made to your Honor that they're worth $50 million. Thank you, your Honor.

MS. BOURKE: Your Honor, one thing? Can I just say -- I forgot to do this in my argument. On that Woodcock letter, Mr. Fox was cross-examined for nearly an hour on that very letter and on the criticism of the clinical trials. It's in Mr. Fox's deposition transcript. It begins at page 75.

THE COURT: Thanks. We'll have a short recess.

(Recess)

THE COURT: If there's any doubt about it, I'm not

going to decide that this afternoon.

MS. BOURKE: Thank you. I was just waiting to be excused.

(Adjourned)